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Diagnostic adequacy of adult bone marrow biopsies in Malawi: A retrospective cohort study

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Background: Bone marrow (BM) sampling is a critical component of clinical care, informing the diagnosis of benign and malignant haematologic disorders.

Objective: We aimed to assess adequacy and characterise the spectrum of diagnoses rendered for BM samples reviewed at Kamuzu Central Hospital in Lilongwe, Malawi.

Methods: We reviewed clinical and pathologic data from all adult BM specimens seen at Kamuzu Central Hospital from 01 June 2012, through 30 June 2024, and utilised R to summarise clinical and diagnostic data.

Results: We identified 602 BM samples, most of which were biopsy-only specimens (n = 335, 56%). Most patients were male (n = 345, 57%), with a median age of 42 years. Of the 539 (90%) patients with known HIV status, 372 (69%) were HIV-uninfected. The most frequent indications for BM sampling were anaemia (n = 188, 31%) and cancer staging (n = 118, 20%). There was no documented indication for 72 cases (12%). Excluding BM samples obtained for cancer staging (n = 118, 20%), there were 403 (83%) diagnostic samples. Of these, 156 (39%) were malignant, with 50 (32%) acute leukaemias and 38 (24%) lymphomas.

Conclusion: We found a high diagnostic yield (85%) of BM samples in this cohort, along with a considerable proportion of new cancer diagnoses (39%) in diagnostic samples taken for reasons other than cancer staging. Non-malignant diagnoses were predominant, yet resources for subcategorising these are limited in our setting.

What this study adds: This study highlights the high diagnostic yield of adult BM samples at Kamuzu Central Hospital and characterises these diagnoses, revealing not only a substantial burden of malignancies but also important gaps in diagnostic capacity.

Keywords: bone marrow biopsy; diagnostic adequacy; haematologic disorders; lymphoproliferative disorders; pathology; Malawi.

Introduction

Bone marrow (BM) sampling is an essential component of diagnosis for numerous haematologic and non-haematologic disorders, allowing for the examination of cellular composition and morphology, structure, and function. Repeated BM evaluation is also necessary for ongoing management of patients with certain haematologic malignancies. Quality of BM sampling can significantly affect the accuracy of diagnostic interpretation, and recommendations for sampling have been published.[1] For example, the World Health Organization recommends that BM core biopsies measure at least 1.5 cm in length, and provides guidance on how best to interpret BM aspirates – differential counts should be performed closely adjacent to particles of undiluted samples.[2]

Anaemia and pancytopaenia, known indications for BM examination, are common in Malawi.[3,4] However, resources for identifying the causes of cytopaenia beyond malaria are limited. For example, nutritional supplementation for iron, folate, and vitamin B12 can be attempted. However, specific laboratory testing and examination of tissue biopsies for other causes is typically not available, especially at more outlying health centres.[5] Bone marrow samples can be interpreted at Kamuzu Central Hospital in Lilongwe, Malawi, because of ongoing collaborative research and laboratory development efforts between the Malawi Ministry of Health, Kamuzu Central Hospital, and the University of North Carolina at Chapel Hill.[6] Of note, Kamuzu Central Hospital is the referral hospital for the Northern and Central Regions of Malawi, with a catchment

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area of approximately 10 million people. It serves as the National Cancer Center, and the Kamuzu Central Hospital Pathology Laboratory is the only public pathology lab in Malawi.

The diagnostic yield and underlying pathology seen in BM biopsies being done in Malawi has not been investigated. Given this gap, we aimed to assess diagnostic adequacy and characterise the diagnoses from BM samples reviewed at Kamuzu Central Hospital over a 12-year period. Given our pathology laboratory capacity and previous observations, we hypothesised that BM sampling in this setting would yield a diagnosis in most (> 50%) cases, and that diagnostic yield would be related to the type and quality of BM sampling.

Methods

Ethical considerations

Our study was approved by the Malawian National Health Sciences Research Committee and the University of North Carolina Institutional Review Board. Waiver of consent was approved for this study since it involved a retrospective analysis of de-identified pathology data from the Kamuzu Central Hospital Pathology Laboratory.

Study design and setting

We conducted a retrospective study of adult (patients ≥ 18 years) BM aspirate and biopsy samples received and interpreted in the pathology laboratory at Kamuzu Central Hospital from 01 June 2012, through 30 June 2024.

Sample and data collection

Relevant clinical and pathological data was extracted from the electronic laboratory information system. Clinical data in the laboratory information system are transcribed from handwritten requisition forms that are filled out by the submitting provider. These forms include age, sex, HIV status, indication for sampling, provider name, clinic where the biopsy was performed, and a free text space which typically includes presenting symptoms and/or peripheral blood counts. As these were done during routine clinical care, the completeness of the forms was inconsistent.

Bone marrow core biopsy specimens were fixed in 10% buffered formalin solution, decalcified, and processed with a Leica TP1020 Automatic Benchtop Tissue Processor (Leica Biosystems, Nussloch, Germany). Sections (3 µm – 5 µm) of the resulting formalin-fixed paraffin-embedded tissue blocks were stained with haematoxylin and eosin, cover-slipped, and examined, per routine clinical protocol. Bone marrow aspirates were smeared onto glass slides and stained with Diff-Quik before cover-slipping. Laboratory personnel conducted routine monitoring and maintenance of all laboratory equipment. The quality of slides and immunohistochemical stains was evaluated by the local pathologists during routine workflow and during weekly teleconference meetings between cancer clinicians and pathologists at Kamuzu Central Hospital and University of North Carolina, as we have described previously.[7]

Primary diagnoses were made by local pathologists, and the vast majority of cases were discussed during weekly multidisciplinary telepathology conferences.[7,8,9] Diagnoses were based on morphologic assessment as well as utilisation of a limited number of immunohistochemical stains (CD45, CK AE1/AE3, MPO, TdT, CD20, CD3, CD138, BLC2, and CD30) as described previously, and acid-fast stain for mycobacteria.[10,11] No flow cytometry, molecular sequencing, or cytogenetic testing was available.

Data analysis

Exported data from the laboratory information system were analysed using R version 4.4.2 (November 2024).[12] Descriptive statistics were completed to summarise data, including proportions for categorical variables, means and standard deviations for normally distributed data, and medians and interquartile ranges for non-normally distributed data.

Results

We identified 602 adult BM samples that were interpreted at the Kamuzu Central Hospital Pathology Laboratory from 01 June 2012, through 30 June 2024 (Table 1). Most specimens were biopsy-only (n = 335, 56%), and most patients were male (n = 345, 57%), with a median age of 42 years (interquartile range 30–54 years). HIV-status was known in 539 cases. Of these, 372 (69%) were HIV-uninfected. The most common indications for BM sampling were anaemia (n = 188, 31%), cancer staging (n = 118, 20%), and

TABLE 1: Clinical and specimen characteristics associated with bone marrow samples (N = 602) evaluated at Kamuzu Central Hospital Pathology Laboratory, June 2012 – June 2024.

Patient demographics	n	%	Median	IQR	Mean	s.d.
Age (years)	-	-	42	30–54	-	-
Male sex	345	57	-	-	-	-
HIV status						
Negative	372	62	-	-	-	-
Positive	167	28	-	-	-	-
Unknown	63	10	-	-	-	-
Specimen type						
Aspirate	70	12	-	-	-	-
Biopsy	335	56	-	-	-	-
Biopsy and aspirate	197	33	-	-	-	-
Specimen characteristics						
Biopsy length (cm)	-	-	1.0	0.5–1.5	-	-
Number of aspirate slides	-	-	-	-	3.1	1.69
Indication for sampling						
Anaemia	188	31	-	-	-	-
Cancer staging	118	20	-	-	-	-
Pancytopaenia	73	12	-	-	-	-
No documented indication	72	12	-	-	-	-
Hepatosplenomegaly	48	8	-	-	-	-
Lymphadenopathy	43	7	-	-	-	-
B-symptoms	36	6	-	-	-	-
Suspected leukaemia	24	4	-	-	-	-

IQR, interquartile range; s.d., standard deviation.

pancytopaenia ($n = 73$, 12%). Indication was not documented in 72 (12%) cases.

Most specimens (n = 512, 85%) were of sufficient quality to receive a discrete diagnosis, and the most common diagnosis was benign or reactive, not otherwise specified ($n = 313$, 52%) (Table 2). Of the 181 (30%) malignant cases, the most common diagnoses were acute leukaemia (n = 65, 11%), with 33 (5%) cases of acute lymphoblastic leukaemia and 32 (5%) cases of acute myeloid leukaemia, and lymphoma (n = 45, 7%), most commonly diffuse large B cell lymphoma (n = 16, 3%). When we excluded BM samples obtained for cancer staging ($n = 118$, 20%), there were 403 (83%) diagnostic samples, 156 of which (39%) were malignant, with 50 (32%) acute leukaemias and 38 (24%) lymphomas.

Based on indication, the highest diagnostic yield was seen in biopsies done for cancer staging (92% yield), and the lowest diagnostic yield was seen in those done for B-symptoms (67% yield) (Figure 1). Biopsies done for suspected leukaemia (n = 24, 4%) and hepatosplenomegaly (n = 48, 8%) had the highest proportion of malignant diagnoses (63% for suspected leukaemia, and 51% for hepatosplenomegaly), while biopsies done for cancer staging ($n = 118$, 20%) and lymphadenopathy (n = 43, 7%) groups had the lowest proportion of malignant diagnoses (23% for cancer staging, and 26% for lymphadenopathy). Figure 2 illustrates the distribution of malignant, non-malignant, and non-diagnostic cases based on indication for BM sampling.

We stratified the cohort by HIV status (Table 2, Figure 3, and Figure 4). The two most common indications for BM sampling in HIV-positive (n = 167) and HIV-negative (n = 372) patients were anaemia (32% for HIV-positive, and 30% for HIV-negative) and cancer staging (26% for HIV-positive, and 19% for HIV-negative). The third most common indication for HIV-positive patients was lymphadenopathy (13%), and for HIV-negative patients, pancytopaenia (13%). The HIV-negative patients had a higher proportion of malignant diagnoses both when samples obtained for cancer staging were included (37% vs 17%) and excluded (39% vs 20%). Of the malignant diagnoses, acute leukaemia was more prominently represented in the HIV-negative group (13% vs 4%). However, when samples obtained for cancer staging were excluded, this difference decreased (32% vs 28%). Lymphoma was the most common malignant diagnosis within the HIV-positive group (n = 10, 34%). However, when cancer staging cases were excluded, acute leukaemia (n = 7, 28%) and lymphoma (n = 7, 28%) accounted for the same proportion of cases.

Bone marrow samples that included both a biopsy and an aspirate (n = 197) had the highest diagnostic yield (91%, $p < 0.001$) compared to samples that were either aspirate ($n = 70$, 71%) or biopsy-only ($n = 335$, 84%) (Table 3). For cases with a BM biopsy, the median biopsy length was 1.0 cm (interquartile range 0.5–1.5), and 38% (n = 186 of 491) were ≥ 1.5 cm. When comparing diagnostic and non-diagnostic

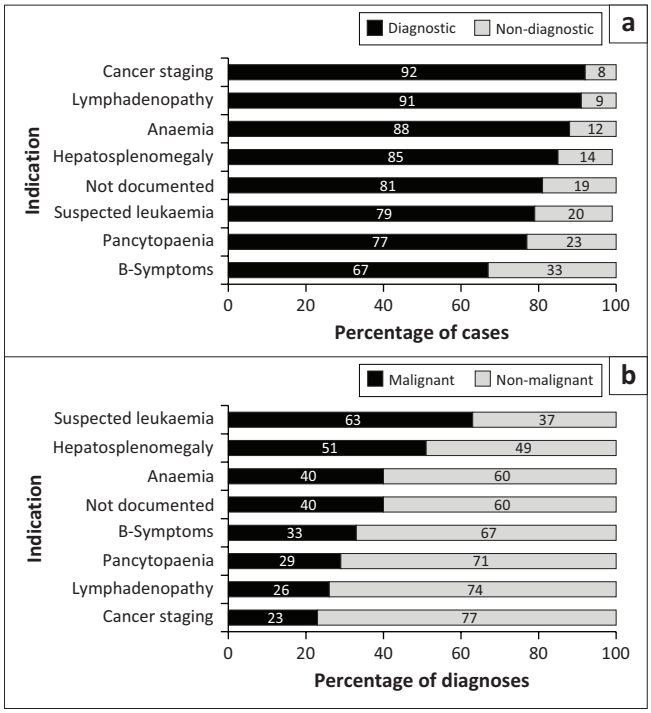


FIGURE 1: Proportion of (a) diagnostic and non-diagnostic cases and (b) malignant and non-malignant diagnoses within each indication for bone marrow sampling for samples evaluated at Kamuzu Central Hospital Pathology Laboratory, June 2012 – June 2024 (N = 602).

TABLE 2: Summary of diagnoses from bone marrow samples (N = 602) evaluated at Kamuzu Central Hospital Pathology Laboratory, June 2012 – June 2024.

Diagnostic category	Total (N = 602)		HIV-positive (n = 167)		HIV-negative (n = 372)		HIV-unknown (n = 63)	
	n	%	*n*	%	*n*	%	*n*	%
Non-malignant	331	55	122	73	172	46	37	58
Benign or reactive, NOS	313	52	120	72	160	43	33	52
Aplastic anaemia	14	2	2	1	9	2	3	5
HIV infection	4	1	0	0	3	1	1	2
Malignant	181	30	29	17	136	37	16	25
Acute leukaemia	65	11	7	4	50	13	8	13
Lymphoma	45	7	10	6	32	9	3	5
Chronic leukaemia	22	4	5	3	17	5	0	0
Multiple myeloma	17	3	3	2	13	3	1	2
Myelodysplastic syndrome	16	3	1	1	14	4	1	2
Carcinoma	16	3	3	2	10	3	3	5
Non-diagnostic	90	15	16	10	64	17	10	16

NOS, not otherwise specified.

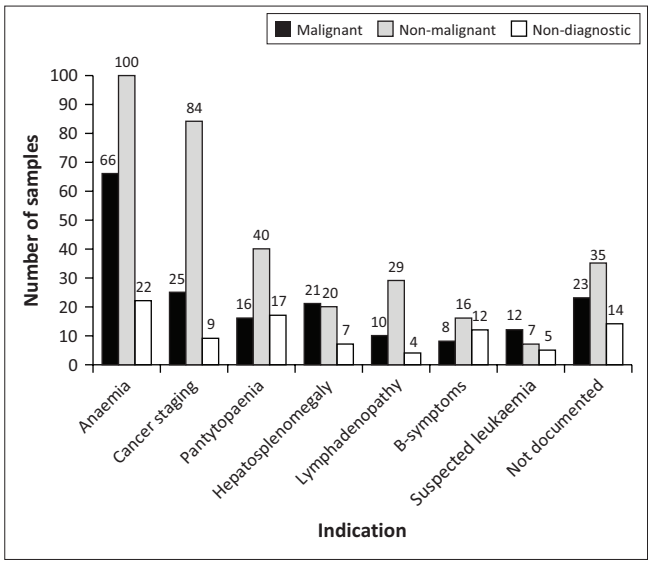


FIGURE 2: Distribution of diagnoses made on bone marrow samples (N = 602) based on indication for sampling, Kamuzu Central Hospital Pathology Laboratory, June 2012 – June 2024.

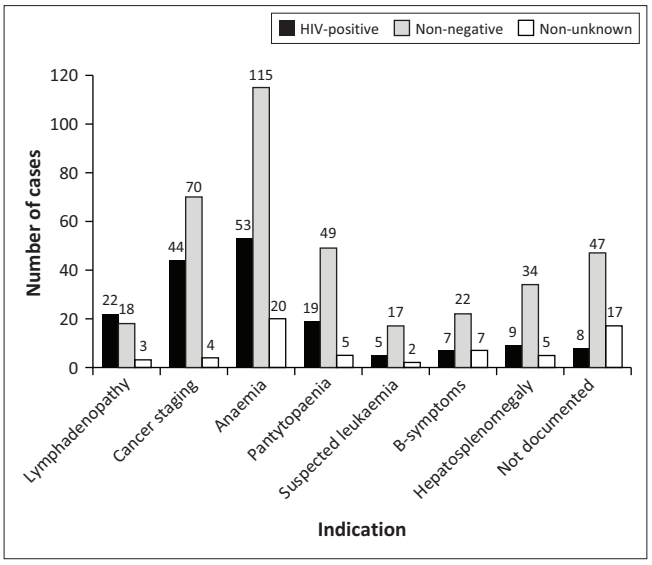
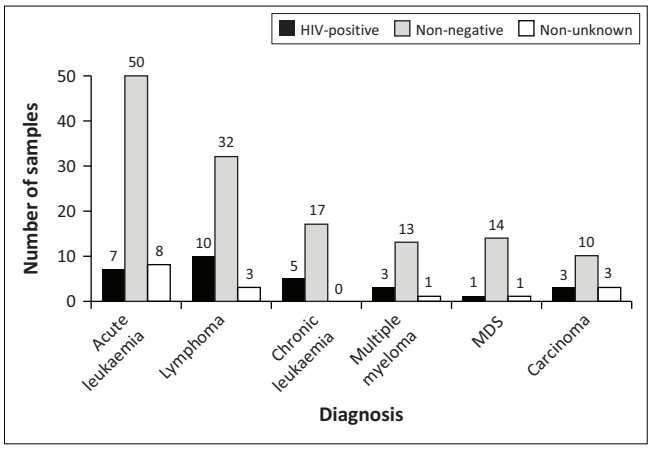


FIGURE 3: Distribution of indications for bone marrow sampling (N = 602 cases) stratified by HIV infection status for bone marrow samples evaluated at Kamuzu Central Hospital Pathology Laboratory, June 2012 – June 2024.

specimens, there was no difference in median biopsy length (p = 0.50) or number of aspirate slides reviewed (p = 0.44). Figure 5 shows images of representative diagnostic and non-diagnostic BM biopsies.

Discussion

Bone marrow characterisation is essential for diagnosing, understanding, and treating haematological disorders.[13] Our objective was to characterise adult BM samples evaluated under routine clinical care at Kamuzu Central Hospital Pathology Laboratory and to assess their adequacy for diagnostic yield. In our setting, 85.0% (n = 512) of all BM samples received a discrete diagnosis. Of these cases, 54% (n = 331) were non-malignant, including most of the samples taken for cancer staging (n = 84 of 118, 77%), while 30% (n = 181) were malignant.



MDS, Myelodysplastic syndrome.

FIGURE 4: Distribution of malignant diagnoses (n = 181 cases) stratified by HIV infection status for bone marrow samples evaluated at Kamuzu Central Hospital Pathology Laboratory, June 2012–June 2024.

TABLE 3: Proportion of diagnostic bone marrow samples (N = 602) depending on specimen type: Aspirate only, biopsy-only, or biopsy with aspirate, Kamuzu Central Hospital Pathology Laboratory, June 2012 – June 2024.

Specimen type	Diagnostic		Non-diagnostic	
	n	%	*n*	%
Aspirate (n = 70)	50	71	20	29
Biopsy (n = 335)	282	84	53	16
Biopsy and aspirate (n = 197)	180	91	17	9

The diagnostic yield of BM samples submitted to Kamuzu Central Hospital was excellent compared to similar studies, some conducted in high-resource settings, reporting inadequacy rates of up to 85%.[14,15,16,17,18,19,20] This is particularly notable when one considers the inherent resource limitations in Malawi, and sparse knowledge of clinical context because of absence of electronic medical records, incomplete requisition forms (12% in our study), and diverse care providers obtaining samples across a large referral area. In addition, the median core biopsy length of BM samples reviewed at Kamuzu Central Hospital was 1.0 cm (interquartile range 0.5 cm – 1.5 cm), which falls shy of the at least 1.5 cm length recommended by the World Health Organization[2,15] and the American Society for Clinical Pathology to ensure reliable interpretation and diagnosis of BM specimens.[1,14,19,21] Despite these issues, 88.0% (n = 530) of our cases had a known biopsy indication, and, as has been reported previously,[22,23] we have a robust multidisciplinary approach to diagnosing patients with suspected haematologic disorders in this setting. Both factors likely contribute to our high diagnostic yield. Nevertheless, ongoing quality assurance measures are needed to optimise specimen quality, ensure accurate clinical information is provided to the laboratory, and standardise diagnostic examination of reporting.[24,25]

The most common diagnosis in our study was benign or reactive, not otherwise specified (n = 313, 52%) which accounted for 95% of the non-malignant diagnoses (n = 331). Increased diagnostic granularity of these cases is an important area of opportunity for the laboratory. While our current

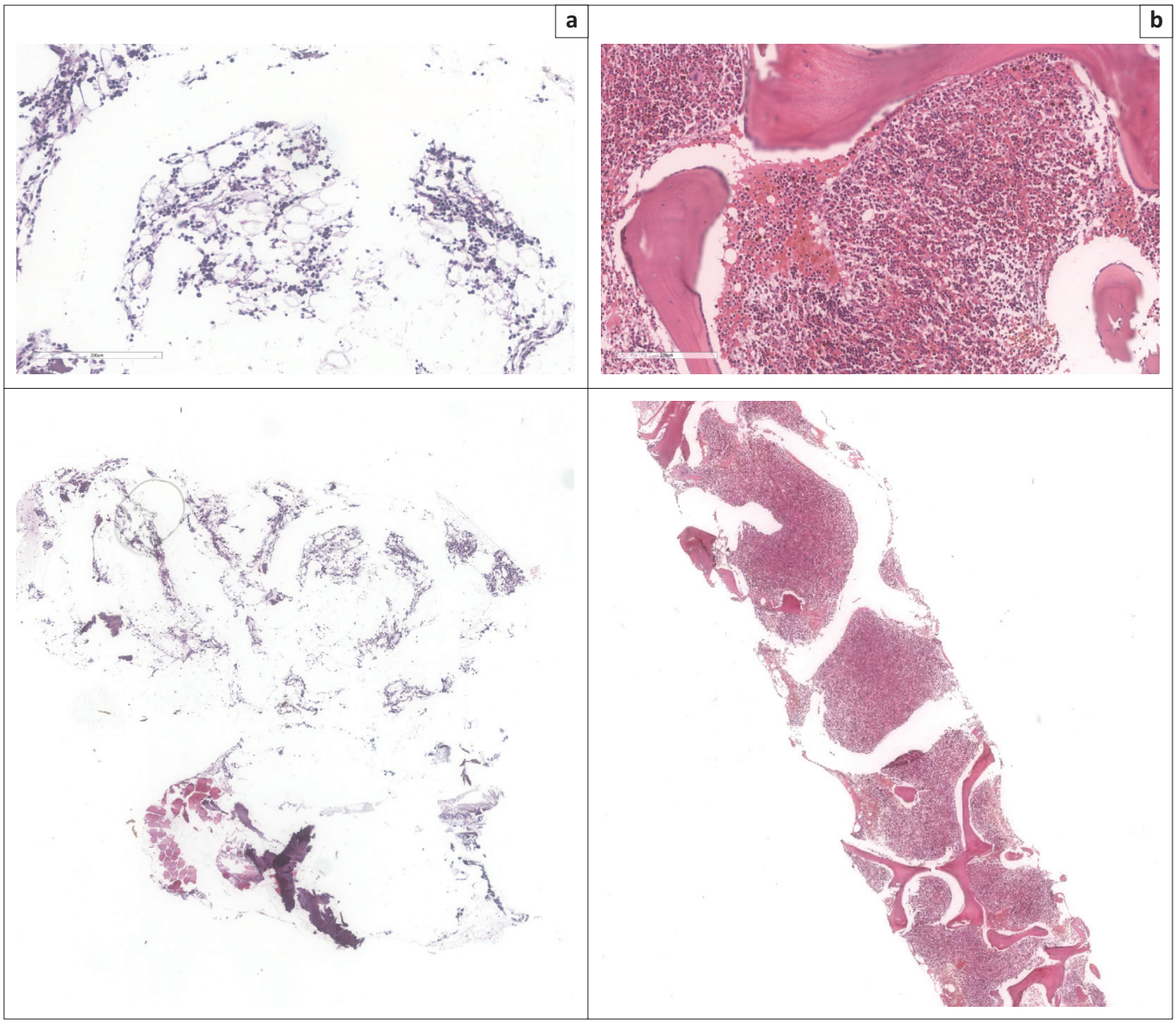


FIGURE 5: Low- and high-power images of representative (a) non-diagnostic and (b) diagnostic bone marrow samples evaluated at Kamuzu Central Hospital Pathology Laboratory, between June 2012 and June 2024. The non-diagnostic biopsy shows a short, fragmented bone marrow biopsy with features suggestive of subcortical sampling. The diagnostic biopsy shows a hypercellular, reactive bone marrow.

system can largely rule out malignancy, we may not be providing a clear or clinically actionable explanation for patients with non-malignant disorders affecting the BM. Proper evaluation requires integrating clinical data with morphologic evaluation of peripheral blood and BM samples, as well as additional ancillary studies. Important ancillary testing techniques not available at the Kamuzu Central Hospital Pathology Laboratory include a larger immunohistochemical staining panel for both infectious and malignant diseases, flow cytometry, and molecular and cytogenetic testing. In addition, reliable clinical testing for nutritional deficiencies, autoimmune disease, and infectious aetiologies are lacking. Strengthening this capacity is essential for providing more granular diagnoses, as well as increasing understanding and improving management of benign haematologic disorders, including neglected diseases in this region such as tropical splenomegaly.

The most common malignant diagnosis in our study was acute leukaemia (n = 65 of 181, 36%), with an equal number of acute lymphoblastic and acute myeloid leukaemias. This is similar to data from other retrospective studies conducted in India (2017) and Pakistan (2016), where leukaemia was diagnosed in at least 21% of BM specimens.[24,25] In addition, a variety of other malignant disorders were identified in our study, including non-Hodgkin lymphoma, Hodgkin lymphoma, chronic myeloid leukaemia, and myelodysplastic syndrome. Overall, there is a significant burden of aggressive malignant diseases in our patient population. Effective, potentially curative treatments are available for many of these malignancies, as we have shown previously.[26,27,28] However, there is an ongoing need to support and expand these treatment modalities, a significant challenge in a resource-limited setting. In addition, more research is needed to further

understand local disease pathogenesis, natural history, and optimal management.

The most common indication for BM sampling in this study was anaemia (n = 188, 31%), and the majority (n = 331, 55%) of BM samples were interpreted as non-malignant. This aligns with our anecdotal impression that a large proportion of the Kamuzu Central Hospital haematology patients are referred for chronic, unexplained anaemia, with or without splenomegaly, and with no definite features of malignancy on clinical exam. In addition, our findings are comparable to a 6-year retrospective study conducted at the Oncology Center – Mansoura University, Egypt, which found that 44.9% (n = 92) of BM samples were interpreted as reactive.[9,29]

Limitations

While we were able to determine a diagnostic yield of BM samples reviewed at Kamuzu Central Hospital and to highlight the distribution of malignant and non-malignant diagnoses within these samples, these findings must be interpreted alongside the limitations of this study. Diagnostic yield was used as a surrogate for BM sample quality, and only total biopsy length was provided instead of total evaluable biopsy length. Moving forward, quality assurance measures can be implemented on the clinical and laboratory sides to maintain optimal sample collection and processing techniques as well as record key variables for ongoing assessment of BM sample adequacy and quality.[22,30,31] Clinical data provided with BM samples were not only limited, but may also be somewhat unreliable, given the nature of sample submission. Lastly, given that this is a hospital-based cohort study, there is inherent selection and referral bias compared to population-based studies. Opportunities to more fully characterise disorders requiring BM sampling across the country of Malawi need to be explored.

Conclusion

Pathologic evaluation of BM samples is essential in the care of patients with both benign and malignant haematologic disorders. We demonstrate a high diagnostic yield of BM biopsies reviewed at Kamuzu Central Hospital, despite significant challenges inherent in our setting, including limited resources and minimal access to clinical data. One of the major strengths of our system is a multidisciplinary approach to diagnosis and patient care. However, identifying ways to increase accessibility to accurate clinical information is needed. In addition, most BM samples in this study were interpreted as benign or reactive, yet we have limited ability to robustly evaluate non-malignant samples. There is an urgent need to develop additional innovative diagnostic resources to better characterise these diseases in Malawi.

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Competing interests

The authors declare that they have no financial or personal relationships that may have inappropriately influenced them in writing this article.

Authors' contributions

Edwards Kasonkanji, Matthew Painschab, Yuri Fedoriw, and Amy Brownlee conceptualised and designed the study. Edwards Kasonkanji and Amy Brownlee prepared the article. Tarsizious Chikaonda reviewed and analysed the data. Yuri Fedoriw, Amy Brownlee, Edwards Kasonkanji, Matthew Painschab, Luke Eastburg, Maurice Mulenga, and Tamiwe Tomoka contributed to collecting and interpreting the clinical data as well as diagnosing the bone marrow samples. Amy Brownlee, Yuri Fedoriw, and Matthew Painschab revised the article and supervised the study. All authors contributed to the article, discussed the results, and approved the final version for submission and publication.

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Data availability

The data that support the findings of this study are available on request from the corresponding author, Amy Brownlee The data are not publicly available due to privacy reasons.

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